VIA FACSIMILE

I hereby certify that this correspondence is being facsimile transmitted to the Commissioner of Patents and Trademarks, Washington, D.C. 20231 on March 28, 2003.

Laurie Olds

Laurie Olds

LUD-5256.4 DIV J[redacted]/NDH (09903230)

#23
JM
7/18/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant	:	Hiles, et al.
Serial No.	:	09/325,095
Filed	:	June 3, 1999
For	:	METHODS FOR DETERMINING EXPRESSION OF A P13 KINASE GENE
Art Unit	:	1645
Examiner	:	J. Hines

March 28, 2003

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231
Attn: SPE Lynette Smith

LETTER
RE: INTERVIEW

An interview has been scheduled for Wednesday, April 2 at 10:00 a.m. in connection with the above referenced case. Applicants confirm the interview, and wish to submit the following for discussion at the interview.

I. POINT 4: DRAWINGS

The examiner indicates "The drawing corrections will no longer be held in abeyance." Applicants request an explanation of this, as there is no indication of allowable subject matter at this time, and it is believed to be inappropriate to require the expense of formal drawings before allowance.

II. POINT 7: THE OBJECTION TO CLAIM 58

The examiner states that claim 58 is improperly dependent because in claim 51, "the sample is already RNA." The sample could include cDNA rather than RNA.

III. POINT 8: THE WRITTEN DESCRIPTION REJECTION

The examiner discusses claims 51 & 59.

APPLICANTS HEREBY AGREE TO CANCEL CLAIM 59.

With respect to the rest of the rejection, as has been pointed out previously, the "sequences" set forth in claim 56 encompass hundreds of sequences. Hence, it is not seen how there is a lack of written description. If this is an enablement rejection, then it is pointed out that the burden is on the examiner to show lack of enablement.

Finally, a transcript of the gene, i.e., the cDNA, is disclosed. See SEQ ID NO: 32, and SEQ ID NO: 35, for example. These were found patentable in U.S. Patent No. 5,846,824. Please see claim 1. Note section (c). Copies of the front page and the issued claims are attached.

IV. POINT 9: THE NEW MATTER REJECTION

It appears that this is a rejection, expressly of claim 59. This being the case, the cancellation of the claim will render it moot. If this is not the case, applicants do not understand the rejection.

V. POINT 10: OMISSION OF ESSENTIAL STEPS

Again, applicants do not understand this rejection, but have agreed to cancel 59.

The claims do recite the use of, e.g., labels. Please see claim 52. Methods, such as PCR, do not necessarily use or need labels.

VI. POINT 11: THE REJECTION UNDER 35 USC §112, SECOND PARAGRAPH

Applicants do not understand this rejection, as the claims are written in the same way as all assay claims are.

Respectfully submitted,

FULBRIGHT & JAWORSKI, L.L.P.

Norman D. Hanson, Esq.
Registration No. 30,946

Letter # 58647

US005846824A

United States Patent [19]

Hiles et al.

[11] Patent Number: 5,846,824

[45] Date of Patent: Dec. 8, 1998

[54] **POLYPEPTIDES HAVING KINASE ACTIVITY, THEIR PREPARATION AND USE**

[75] Inventors: **Ian D. Hiles; Michael J. Fry; Ritu Dhand; Michael D. Waterfield; Peter J. Parker; Masayuki Otsu; George Panayoutou; Stefano Volinia; Ivan Gout**, all of London, England

[73] Assignee: **Ludwig Institute for Cancer Research**, New York, N.Y.

[21] Appl. No.: **780,872**

[22] Filed: **Jan. 9, 1997**

Related U.S. Application Data

[62] Division of Ser. No. 162,081, Feb. 7, 1994.

[51] **Int. Cl.**[6] **C12N 5/10**; C12N 5/16; C12N 15/54; C12N 15/63

[52] **U.S. Cl.** **435/348**; 435/320.1; 435/325; 536/23.2; 536/24.3

[58] **Field of Search** 536/23.2, 23.5, 536/24.3; 435/320.1, 325, 348, 252.3, 254.11

[56] **References Cited**

PUBLICATIONS

Otsu et al., Cell 65:91–104, 1991.

Primary Examiner—Eric Grimes
Attorney, Agent, or Firm—Fulbright & Jaworski

[57] **ABSTRACT**

This invention relates to new polypeptides which exhibit kinase activity or, more specifically, which show phosphoinositide (PI) 3-kinase activity. Such polypeptides are involved in pathways responsible for cellular growth and differentiation. An isolated polypeptide which possesses PI3-kinase activity when produced by recombinant production in insect cells is disclosed.

8 Claims, 76 Drawing Sheets

-continued

(C) STRANDEDNESS: single
(D) TOPOLOGY: linear

(xi) SEQUENCE DESCRIPTION: SEQ ID NO: 50:

Gly	Asp	Asp	Leu	Arg	Gln	Asp	Leu	Leu	Gln	Ile	Ile	Met	Gln	Leu	Asp
1				5					10					15	
Leu	Pro	Tyr	Leu	Thr	Gly	Gly	Ile	Gln	Ile	Asn	Gly	Ile	Gly	Leu	Asn
			20					25					30		
Ile	Asp	Phe	Val	Ser	Cys	Ala	Gly	Tyr	Cys	Val	Thr	Tyr	Ile	Leu	Gly
		35					40					45			
Gly	Asp	Arg	His	Asp	Asn	Gly	Leu	Phe	His	Ile	Asp	Phe	Gly		
	50					55					60				

We claim:

1. An isolated nucleic acid molecule which encodes the catalytic (110 kD) subunit of PI-3 kinase, selected from the group consisting of:

(a) the nucleotide sequence set forth in SEQ ID NO: 32.

(b) the nucleotide sequence set forth in SEQ ID NO: 35. and

(c) a nucleotide sequence which hybridizes to the complement of at least one of (a) and (b).

2. The isolated nucleic acid molecule of claim 1. wherein said isolated nucleic acid molecule encodes a polypeptide consisting of the amino acid sequence encoded by the nucleotide sequence set forth in SEQ ID NO: 32 SEQ ID NO: 35.

3. The isolated nucleic acid molecule of claim 1. wherein said isolated nucleic acid molecule encodes a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO: 37.

4. Expression vector comprising the isolated nucleic acid molecule of claim 2. operably linked to a promoter.

5. The expression vector of claim 4. wherein said promoter is regulatable.

6. Host cell transformed or transfected with the expression vector of claim 4.

7. The host cell of claim 6. wherein said host cell is an insect cell.

8. Isolated nucleic acid molecule consisting of any one of

(a) nucleotides 487–525 of SEQ ID NO: 32.

(b) nucleotides 876–1011 of SEQ ID NO: 32.

(c) nucleotides 1321–1392 of SEQ ID NO: 32.

(d) nucleotides 1864–1944 of SEQ ID NO: 32.

(e) nucleotides 1969–2016 of SEQ ID NO: 32.

(f) nucleotides 2035–2097 of SEQ ID NO: 32.

(g) nucleotides 2134–2160 of SEQ ID NO: 32.

(h) nucleotides 2602–2646 of SEQ ID NO: 32.

(i) nucleotides 2653–2724 of SEQ ID NO: 32.

(j) nucleotides 2773–2823 of SEQ ID NO: 32.

(k) nucleotides 2845–2898 of SEQ ID NO: 32.

(l) nucleotides 2959–3030 of SEQ ID NO: 32.

(m) nucleotides 3091–3189 of SEQ ID NO: 32. and

(n) nucleotides 3163–3189 of SEQ ID NO: 32.

* * * * *

GAU

FULBRIGHT & JAWORSKI L.L.P.
A REGISTERED LIMITED LIABILITY PARTNERSHIP
666 FIFTH AVENUE, 31ST FLOOR
NEW YORK, NEW YORK 10103-3198
WWW.FULBRIGHT.COM

FACSIMILE TRANSMISSION

DATE: March 28, 2003 **MATTER NUMBER:** 09903230

RECIPIENT(S):	FAX NO.:	PHONE NO.:
Attn: SPE Lynette Smith, Examiner J. Hines USPTO, Group 1645	703-308-4242	FAX RECEIVED

MAR 28 2003

GROUP 1600

OFFICIAL

FROM: Norman Hanson **USER ID:** NH01030 **FLOOR:** 24

PHONE: (212) 318-3168 **FAX:** (212) 318-3400

RE: LUD 5256.4

NUMBER OF PAGES WITH COVER PAGE: 5

Message:

CAUTION - CONFIDENTIAL

IF YOU DO NOT RECEIVE ALL OF THE PAGES, PLEASE CALL _____ AT _____ AS SOON AS POSSIBLE.